

AD \_\_\_\_\_

Award Number: DAMD17-02-1-0186

TITLE: Use of Tele-technology for Heart Disease Management:  
Improving Clinical and Economic Outcomes in a Managed  
Care Population

PRINCIPAL INVESTIGATOR: Blain H. Yoshinobu, Ph.D.

CONTRACTING ORGANIZATION: Henry M. Jackson Foundation for the  
Advancement of Military Medicine  
Rockville, Maryland 20852-1428

REPORT DATE: April 2003

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;  
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

**REPORT DOCUMENTATION PAGE**Form Approved  
OMB No. 074-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

**1. AGENCY USE ONLY**  
(Leave blank)**2. REPORT DATE**  
April 2003**3. REPORT TYPE AND DATES COVERED**  
Annual (7 Mar 2002 - 6 Mar 2003)**4. TITLE AND SUBTITLE**Use of Tele-technology for Heart Disease Management:  
Improving Clinical and Economic Outcomes in a Managed Care  
Population**5. FUNDING NUMBERS**

DAMD17-02-1-0186

**6. AUTHOR(S)**

Blain H. Yoshinobu, Ph.D.

**7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)**Henry M. Jackson Foundation for the  
Advancement of Military Medicine  
Rockville, Maryland 20852-1428

E-Mail: blain.h.yoshinobu@tamc.chcs.amedd.army.mil

**8. PERFORMING ORGANIZATION  
REPORT NUMBER****9. SPONSORING / MONITORING****AGENCY NAME(S) AND ADDRESS(ES)**U.S. Army Medical Research and Materiel Command  
Fort Detrick, Maryland 21702-5012**10. SPONSORING / MONITORING  
AGENCY REPORT NUMBER****11. SUPPLEMENTARY NOTES**

20030929 008

**12a. DISTRIBUTION / AVAILABILITY STATEMENT**

Approved for Public Release; Distribution Unlimited

**12b. DISTRIBUTION CODE****13. ABSTRACT (Maximum 200 Words)**

Use novel tele-technology web services incorporated into business process redesign and disease state management to improve the disease management and outcomes of patients with Diabetes, Hypertension, Hyperlipidemia (risk factors for Heart Disease which is the number one cause of death in the United States per World Health Organization, 1998 statistics). Providers (physicians, nurses, pharmacists, educators) and patients will be tied together through improved automation, knowledge management, and disease management processes that link all of the sites of care (inpatient, outpatient, home-based patient monitoring). Our hypothesis is that compared to pre-implementation of tele-technology disease management, there will be a statistically and clinically significant improvement in health care markers of disease treatment, as well as cost, post-implementation of tele-technology disease management.

**14. SUBJECT TERMS**

No Subject Terms Provided.

**15. NUMBER OF PAGES**

11

**16. PRICE CODE****17. SECURITY CLASSIFICATION  
OF REPORT**

Unclassified

**18. SECURITY CLASSIFICATION  
OF THIS PAGE**

Unclassified

**19. SECURITY CLASSIFICATION  
OF ABSTRACT**

Unclassified

**20. LIMITATION OF ABSTRACT**

Unlimited

## Table of Contents

Cover.....	1
SF 298.....	2
Table of Contents.....	3
Introduction.....	4
Technical Objectives.....	4
Key Research Accomplishments.....	6
Reportable Outcomes.....	6
Conclusions.....	6
References.....	8
Appendices.....	11

## INTRODUCTION

Use novel tele-technology web services incorporated into business process redesign and disease state management to improve the disease management and outcomes of patients with Diabetes, Hypertension, Hyperlipidemia (risk factors for Heart Disease which is the number 1 cause of death in the United States per World Health Organization, 1998 statistics). Providers (physicians, nurses, pharmacists, educators) and patients will be tied together through improved automation, knowledge management, and disease management processes that link all of the sites of care (inpatient, outpatient, home-based patient monitoring). Our hypothesis is that compared to pre-implementation of tele-technology disease management, there will be a statistically and clinically significant improvement in health care markers of disease treatment, as well as cost, post-implementation of tele-technology disease management.

### Specific Aims

(1) Design and implement a tele-technology disease state management web application (by adding additional functionality to an existing provider/case manager disease state management web application called CEO).

(2) Measure the effect of tele-technology disease management on clinical indicators of diseases and cost of healthcare. These metrics include utilization and cost (number of admissions, length of hospital stay, number of outpatient visits, cost of all services), patient outcomes (blood pressure, cholesterol profile, hemoglobin a1c, microalbuminuria/proteinuria), guideline adherence (patient outcome variables as benchmarked against the threshold values and frequency of testing put forth by national clinical practice guidelines, see Appendix 1).

## BODY

### A. Statement Of Work

#### 1. Prior to Study

- (a) IRB Protocol/Consent Approval process begins (submit for September 2001 IRB)
- (b) CRDA Approval process begins (submit September 2001)
- (c) Funding received (January 2002)
- (d) Hiring of Programmer, Research Coordinator, Administrative Assistant (January 2002)
- (e) Complete client/server CEO web application (May 2002)
- (f) Order iPAQs for Testing. Test web application. (April 2002)
- (g) Hiring of LPN, Clinical Pharmacist Case Manager, Tech Support (April 2002)

#### 2. Study Starts (May 2002)

- (a) Screen patients for inclusion/exclusion criteria using CEO
- (b) Enrollment of patients from Tripler (Adult Medicine and Family Practice Clinics) and Schofield (Family Practice Clinic)
- (c) Gather 1 year baseline data for included patients

- (d) Three month data analysis
- (e) Six month data analysis
- (f) Nine month data analysis
- (g) Twelve month data analysis
- (h) Complete study (November 2003)
- (i) Complete data gathering (November-December 2003)
- (j) Complete data analysis and reports (April 2004)
- (k) Presentation/Publication (June 2004)

B. Negative as well as positive findings. Include problems in accomplishing any of the tasks.

Currently there has been no enrollment of patients into the study due to:

1. Virtual Health Solutions, Inc. and Computer Training Academy (CTA) are currently in the development of producing and deploying the software to support the solution for the current Handheld Personal Digital Assistant/Pocket PC for the Patients at home monitoring: Blood Pressure, blood glucose, cholesterol, side effects, compliance email, appointment reminders, messages from case managers, and provider alerts.

2. Currently, Tripler Army Medical Center (TAMC) Information Management Department (IMD) will be implementing a transition from ACPG to ICDB. Our current study was budgeted for using the existing technology built on ACPG. With this change in the institution's platform, our CEO technical lead Dr. Jai, has estimated an increase in the cost to adapt our technology to the new platform ICDB. This has also been confirmed with CTA who is currently working with Dr. Underwood and Joel Tanaka through Tripler's Information Management Department (IMD) and also Dr. Jai to produce back-end support for the pocket PC. The pocket PC software (created by VHSi) will be responsible for capturing and transmitting patient data through a wireless connection to Internet servers at TAMC. Patients will then be able to enter vital statistics (like blood pressure) from home (or wherever they are), into the PC, which is connected to the internet using wireless technology. The computers at TAMC will receive the values and inform Case Managers and other providers. Further, communications will be possible from the providers to the patient and automated "rules" can generate alerts and perform other functions based upon detection of specific value ranges.

3. The protocol performance site as well as the subaward will be moved from Tripler Army Medical Center to the Portland VA which has a platform which would accommodate our current research study at a minimal cost for completion of our technology and patient enrollment, per The Henry M. Jackson Foundation for the Advancement of Military Medicine, Inc. through the DoD Congressionally Directed Medical Research and Material Command, which has been approved per Dr. Sherry Ward, Grants Manager, and also Ms. Patricia Evans.

## KEY RESEARCH ACCOMPLISHMENTS

Virtual Health Solutions, Inc. and Computer Training Academy (CTA) are currently in the development of producing and deploying the software to support the solution for the current Handheld Personal Digital Assistant/Pocket PC for the patients at home monitoring: blood pressure, blood glucose, cholesterol, side effects, compliance email, appointment reminders, messages from case managers, and provider alerts. Currently, we will be Beta testing in June and July and also there has been a relationship with Microsoft Development in the process of development of PDA capabilities

## REPORTABLE OUTCOMES

Virtual Health Solutions, Inc. and Computer Training Academy (CTA) are currently in the development of producing and deploying the software to support the solution for the current Handheld Personal Digital Assistant/Pocket PC for the patients at home monitoring: blood pressure, blood glucose, cholesterol, side effects, compliance email, appointment reminders, messages from case managers, and provider alerts. Currently, there may be additional support of Microsoft development with the PDA device.

## CONCLUSIONS

### Evaluation and Analysis of Results

1. Data analysis will be performed on aggregate data with all patient identifiers removed.
2. Health Economics: The institutional perspective will be used and so the pertinent direct costs to the institution will be calculated based upon health system resource utilization of laboratory tests, radiology procedures, prescriptions, appointments, emergency room visits, and hospitalizations.
3. The clinical indicators will be compared using appropriate statistical techniques:
  - (a) For nominal data (e.g. whether patients meet the ADA hgb1ac goal for good control) we will use a non-parametric method, Chi-square analysis-of-contingency table.
  - (b) For interval data, we will test the assumption of whether the population values of a specific indicator (e.g. low density lipoprotein cholesterol) are normally distributed. If so, we will use an unpaired t-test. Otherwise, we will assign ranks and use a non-parametric method, Mann-Whitney rank-sum test.
  - (c) For ordinal data (psychology of compliance assessment tool), Mann-Whitney rank-sum test.

Power Analysis: Enrollment based upon population standard deviation 1.5% HgbA1c, Power 0.80, Alpha 0.05 and ability to detect 0.5% difference between groups and 20% drop out rate. 36% of patients should have hyperlipidemia in order to detect a 20 mg/dl difference between before and after, based upon standard deviation 36 mg/dl LDL, Power 0.80, Alpha 0.05, 20% drop out rate. Preliminary study using CEO determined that 44% of our military beneficiary population in Hawaii of diabetics also have hypertension. Also, 29% have hypercholesterolemia.

## REFERENCES

1. World Health Organization statistics, 1998.
2. Department of Defense Pharmacoeconomic Center web page.  
<http://www.pec.ha.osd.mil/>. Department of Defense Pharmacoeconomic Center. 5-7-2001. Ref Type: Internet Communication.
3. Ambulatory Data System data for Army, Navy and Air Force, Region 12, November 1999
4. CEIS, CHCS I or II and the automated clinical practice guideline initiatives. 1998. Ref Type: Personal Communication.
5. Kohn L, Corrigan J, Donaldson M: To Err Is Human: Building a Safer Health System. National Academy Press, Washington DC, 2000.
6. Reason J: Human Error. Cambridge: Cambridge University Press 1990.
7. Kuntz KM, Lee TH: Cost-effectiveness of accepted measures for intervention in coronary heart disease. *Coron Artery Dis* 6:472-478, 1995
8. Erhardt LR: The Essence of Effective Treatment and Compliance is Simplicity. *American Journal of Hypertension* 12:105S-110S, 1999
9. Jans M, Schellevis F, Van Hensbergen W, Van Emden T, Van Eijk J: Management of asthma and COPD patients: feasibility of the application of guidelines in general practice. *International Journal for Quality in Health Care* 10:27-34, 1998
10. Streja D, Rabkin S: Factors Associated With Implementation of Preventive Care Measures in Patients with Diabetes Mellitus. *Archives of Internal Medicine* 159:294-302, 1999
11. Deutsch S, Denton M, Borenstein J: Clinical practice guidelines: A tool to help provide quality care. *Geriatrics* 53:57, 61-4, 70,-73-75, 1998
12. Fletcher R, Fletcher S: Clinical practice guidelines. *Annals of Internal Medicine* 113:645-646, 1990
13. Zielstorff RD: Online Practice Guidelines: Issues, Obstacles, and Future Prospects. *Journal of the American Medical Informatics Association* 5:227-236, 1998
14. Cabana M, Rand C, Powe N, Wu A, Wilson M, Abboud P, Rubin H: Why Don't Physicians Follow Clinical Practice Guidelines? A Framework for Improvement. *JAMA* 282:1458-1465, 1999
15. Picken HA, Greenfield S, Teres D, Hirway PS, Landis JN: Effect of Local Standards on the Implementation of National Guidelines for Asthma. *Journal of General Internal Medicine* 13:659-663, 1998
16. Ely JW, Goerdt CJ, Bergus GR, West CP, Dawson JD, Doebbeling BN: The Effect of Physician Characteristics on Compliance with Adult Preventive Care Guidelines. *Family Medicine* 30:34-39, 1998
17. Heath K, Hogg R, Singer J, Schechter M, O'Shaughnessy M, Montaner J: Adherence to clinical guidelines for the therapeutic management of HIV disease. *Clinical and Investigative Medicine* 20:381-387, 1997
18. Meng Y, Leung K, Berkgigler D, Halbert R, Legorreta A: Compliance with US asthma management guidelines and specialty care: a regional variation or national concern? *Journal of Evaluation in Clinical Practice* 5:213-221, 1999



19. Halm EA, Atlas SJ, Borowsky LH, Benzer TI, Metlay JP, Chang Y, Singer DE: Understanding Physician Adherence With a Pneumonia Practice Guideline Effects of Patient, System, and Physician Factors. *Archives of Internal Medicine* 160:98-104, 2000
20. Lomas J, Anderson G, Domnick-Pierre K, Vayda E, Enkin M, Hannah W: Do Practice Guidelines Guide Practice. *The New England Journal of Medicine* 321:1306-1311, 1989
21. Balas E, Weingarten S, Garb C, Blumenthal D, Boren S, Brown G: Improving Preventive Care by Prompting Physicians. *Archives of Internal Medicine* 160:301-308, 2000
22. James P, Cowan T, Graham R, Majeroni B: Family Physicians' Attitudes About and Use of Clinical Practice Guidelines. *Journal of Family Practice* 45:341-347, 1997
23. McCullough D, Price M, Hindmarsh M, Wagner E: A Population-Based Approach to Diabetes Management in a Primary Care Setting: Early Results and Lessons Learned. *Effective Clinical Practice* 1:12-22, 1998
24. Frankel H, Fitzpatrick M, Gaskell S, Hoff W, Rotondo M, Schwab C: Strategies to Improve Compliance with Evidence-Based Clinical Management Guidelines. *Journal of the American College of Surgeons* 189:533-538, 1999
25. Goethe JW, Schwartz HI, Szarek BL: Physician Compliance with Practice Guidelines. *Connecticut Medicine* 61:553-558, 1997
26. Holmboe E, Scranton R, Sumption K, Hawkins R: Effect of Medical Record Audit and Feedback on Residents' Compliance with Preventive Health Care Guidelines. *Academic Medicine* 73:901-903, 1998
27. Lobach D: Electronically Distributed, Computer-Generated, Individualized Feedback Enhances the Use of a Computerized Practice Guideline. *Proceedings AMIA Annual Symposium* 493-497, 1996
28. Cannon D, Allen S: A Comparison of the Effects of Computer and Manual Reminders on Compliance with a Mental Health Clinical Practice Guideline. *JAMA* 283:196-203, 2000
29. Emslie C, Grimshaw J, Templeton A: Do clinical guidelines improve general practice management and referral of infertile couples? *British Medical Journal* 306:1728-1731, 1993
30. Rossi R, Every N: A Computerized Intervention to Decrease the Use of Calcium Channel Blockers in Hypertension. *Journal of General Internal Medicine* 12:672-678, 1997
31. Corb GJ, Liaw Y, Brandt CA, Shiffman RN: An Object-Oriented Framework for the Development of Computer-Based Guideline Implementations. *Methods of Information in Medicine* 38:148-153, 1999
32. Stolte J, Ash J, Chin H: The dissemination of clinical practice guidelines over an intranet: an evaluation. *Proceedings AMIA Annual Symposium* 960-964, 1999
33. Chute C: Standards move to center stage. *MD Computing* 16:29-32, 1999
34. Davis D, Taylor-Vaisey A: Translating guidelines into practice. A systematic review of theoretic concepts, practical experience and research evidence in the adoption of clinical practice guidelines. *Canadian Medical Association Journal* 157:408-416, 1997
35. Morgan MM, Goodson J, Barnett GO: Long-term Changes in Compliance with Clinical Guidelines Through Computer-based Reminders. *Proceedings AMIA Annual Symposium* 493-497, 1998
36. Shiffman R, Liaw Y, Navedo D, Freudigman K: User satisfaction and frustration with a handheld, pen-based guideline implementation system for asthma. *Proceedings AMIA Annual Symposium* 940-944, 1999

37. Stone TT, Kivlahan CH, Cox KR: Evaluation of Physician Preferences for Guideline Implementation. *American Journal of Medical Quality* 14:170-177, 1999
38. Tang PC, LaRosa MP, Newcomb C, Gorden SM: Measuring the Effects of Reminders for Outpatient Influenza Immunizations at the Point of Clinical Opportunity. *Journal of the American Medical Informatics Association* 6:115-121, 1999
39. Tsui F-C, Wagner M, Thompson ME: Implementing NCEP Guidelines in a Web-based Disease-Management System. *Proceedings AMIA Annual Symposium* 764-768, 1997
40. Weingarten S, Riedinger M, Conner L, Lee T, Hoffman I, Johnson B, Ellrodt A: Practice Guidelines and Reminders to Reduce Duration of Hospital Stay for Patients with Chest Pain. *Annals of Internal Medicine* 120:257-263.
41. Schriger D, Baraff L, Rogers W, Cretin S: Implementation of clinical guidelines using a computer charting system. Effect on the initial care of health care workers exposed to body fluids. *JAMA* 278:1585-1590, 1997
42. ADA home page. <http://www.diabetes.org>. American Diabetes Association. 6-1-2000. Ref Type: Internet Communication
43. NHLBI National Cholesterol Education Program web page. [http://www.nhlbi.nih.gov/guidelines/cholesterol/atp\\_ii.htm](http://www.nhlbi.nih.gov/guidelines/cholesterol/atp_ii.htm). National Heart, Lung, and Blood Institute. 5-7-2001. Ref Type: Internet Communication.
44. NHLBI Joint National Committee on High Blood Pressure web page. <http://www.nhlbi.nih.gov/guidelines/hypertension/jncintro.htm>. National Heart, Lung, and Blood Institute. 5-7-2001. Ref Type: Internet Communication.

# APPENDIX

